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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 26, 2004

Terry Fredeking, President
Antibody Systems, Inc.
1901 Norwood Drive
Hurst, Texas 76054

Dear Mr. Fredeking,

I am writing to you in response to your letter of December 31, 2003 to Patricia Holobaugh, Chief of the Bioresearch Monitoring Branch in the Center for Biologics Evaluation and Research (CBER). Ms. Holobaugh referred your letter to CBER's Access Litigation and Freedom of Information Branch (ALFOI) for response because in your letter you request that your name and the name of your company, Antibody Systems, Inc. (Antibody Systems), be redacted from all sections of Warning Letter CBER-03-010, which is currently posted on the FDA website. I have reviewed your letter and am denying your request, for the reasons below.

The crux of your complaint is that the Warning Letter "inappropriately conveys the impression that the deficiencies attributable to the North Texas IRB may also be attributable to Antibody Systems, Inc. and Terry Fredeking its president." In the letter FDA was clear that the inspection was limited to records "relating to the operations of the North Texas Institutional Review Board" and that the purpose of the inspection was to determine if the IRB's procedures for protection of human subjects complied with FDA regulations. FDA also clearly stated that it "addressed the letter to you because the IRB was established to review only studies sponsored by, or conducted under contracts to, Antibody Systems, Inc.," and, as the inspection confirmed, the IRB in fact reviewed only studies in which Antibody Systems was either the sole or co-sponsor. As the Warning Letter further pointed out, because the IRB had no Chair at the time that FDA sent the letter, you were the most appropriate addressee, given that "the inspection showed that you have played a significant role in the IRB's operations and appear to be the most responsible party regarding the operations of this IRB."

That conclusion is fully supported by the record from the inspection. For example, Dr. Dishon, the former IRB Chairman, told investigators that Antibody Systems created the IRB, selected its members, and handled most of the IRB's administrative tasks. Among those tasks were maintaining IRB meeting minutes, composing approval letters for Dr. Dishon's signature, scheduling IRB meetings, and distributing study-related materials for IRB members to review.

Under FDA regulations the "parent institution is presumed to be responsible for the operation of an IRB, and the [FDA] will ordinarily direct any administrative action . . . against the institution." 21 C.F.R. § 56.120(c). Although the "institution" is often a hospital or university with which an IRB is associated, the regulations define "institution"

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as "any public or private entity or agency . . . ." 21 C.F.R. § 56.102(f). As FDA explained in the preamble to the human subject protection regulations, FDA intentionally defined "institution" broadly, in conformance with the definition in Department regulations, because "institutional review" is no longer strictly tied to "institutions" like hospitals and other health-care establishments. 46 Fed. Reg. 8958, 8963 (Jan. 27, 1981); *see also* 43 Fed. Reg. 35186, 35188 (Aug. 8, 1978 proposed rule). Rather, IRB review is now required for "all clinical investigations that support applications for research or marketing permits for products regulated by FDA," regardless of the type of "institution" that conducts the investigation.

Accordingly, the regulations define an IRB as "any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects." 21 C.F.R. §§ 56.102(g) (emphasis added). FDA adopted that definition because "[t]he agency recognizes that an IRB is created by and is responsible to the institution. Consequently, it is the duty of the institution to assure that its IRB meets the obligations imposed by Federal statute and regulations." 46 Fed. Reg. at 8972. Here, Antibody Systems created North Texas IRB and designated North Texas IRB to review its biomedical research. Therefore, Antibody Systems is the "institution" and was responsible for ensuring that the IRB's violations were corrected and do not recur.

You contend in your letter that redacting your name and your company's name from the Warning Letter would be "consistent with FDA's operating policies concerning the purging of confidential commercial information and information to protect the privacy of individuals in copies of warning letters, which are made public pursuant to FOI requests or when placed on the internet." To the contrary, FDA does not redact the names of companies or their president when sending Warning Letters for violations observed at IRBs that review those companies' research. *See, e.g.,* Warning Letter to Robert W. Rubin, Ph.D., President/CEO, Lovelace Respiratory Research Institute, Inc., dated 2/27/03 (http://www.fda.gov/foi/warning_letters/g3840d.htm). Moreover, redacting your name and the name of your company from Warning Letter CBER-03-010 is not supported by the Freedom of Information Act or our regulations, as interpreted by case law, because they do not constitute confidential commercial information, and because disclosing them does not constitute a clearly unwarranted invasion of personal privacy. *See* 5 U.S.C. §§ 552(b)(4), (b)(6); 21 C.F.R. §§ 20.61, 20.63.

First, as to your company, 21 C.F.R. § 20.63(c) states that "[r]equests for deletion of business or product names prior to disclosure of any record to the public shall not be granted on the ground of privacy, but such deletion may be justified under another exemption established in this subpart, e.g., the exemption for trade secrets and confidential commercial or financial information under § 20.61." Therefore, privacy is not a valid basis for redacting Antibody Systems' name from the letter. *See National Parks & Conservation Ass'n v. Kleppe,* 547 F.2d 673, 685 n. 44 (D.C. Cir. 1976).

As to the possibility that the relationship between Antibody Systems and North Texas IRB is confidential commercial information under § 20.61, such information is

considered "confidential" only "if disclosure of the information is likely to have either of the following effects: (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained." *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974). As to the first prong of that definition, FDA regulations require companies that sponsor clinical trials of investigational drugs to have IRBs review their clinical trials, 21 C.F.R. § 56.103, and require that records of the research proposals that an IRB reviews, and of the IRB's actions in reviewing that research, be made accessible to FDA, 21 C.F.R. § 56.115(b). Therefore, FDA can readily find out which IRB has reviewed each sponsor's clinical trials, and disclosing that information publicly will not impair the Government's ability to obtain this necessary information in the future.

Of course, the Government may not disclose that information if doing so would trigger the second definition of "confidential," namely that it is likely to cause substantial harm to the competitive position of the person from whom the information was obtained. Harming a company's competitive position, however, has a very specific meaning. As the Court of Appeals for the District of Columbia Circuit has explained, "[t]he important point for competitive harm in the FOIA context . . . is that it be limited to harm flowing from the affirmative use of proprietary information by competitors" and that this "should not be taken to mean simply any injury to competitive position, as might flow from customer or employee disgruntlement . . . ." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1291 n.30 (D.C. Cir. 1983) (emphasis and internal citation omitted).

You have not provided any basis for claiming that the identity of the IRB that Antibody Systems used to review its research is proprietary information, or that competitors could affirmatively use that information to give them an advantage. An IRB's purpose is to protect the rights and welfare of human subjects involved in clinical investigations. 21 C.F.R. § 56.101(a). Federal regulations require that IRBs be free of conflicts of interest so that they may perform that purpose independently. 21 C.F.R. § 56.107(e). The IRB that a sponsor uses should not give a company any competitive advantage over its competitors. Thus, competitors should not be able to gain any competitive advantage through any affirmative use of the knowledge that Antibody Systems used North Texas IRB.

Moreover, harm to a company's reputation flowing from embarrassing disclosures or bad publicity, rather from a competitor's use of that proprietary information, does not qualify as competitive harm. *See General Elec. Co. v. NRC*, 750 F.2d 1394, 1402-03 (7th Cir. 1984); *CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1154 (D.C. Cir. 1987). Consequently, embarrassment that your company might suffer when others read the Warning Letter is not the type of competitive harm that can justify redacting Antibody Systems' name.

For those reasons, we are not redacting Antibody Systems' name from the letter.

As to your name, although unlike businesses, individuals may have privacy interests protected by FOIA and FDA regulations, individuals may not assert privacy interests in information that they themselves have made public, or that they have authorized others to make public. *See Niagara Mohawk Power Corp. v. United States Dep't of Energy,* 169 F.3d 16, 19 (D.C. Cir. 1999). In your case, your company's own website discloses that you are Antibody Systems' President, and therefore we are not redacting your name on privacy grounds. Similarly, FDA is not redacting your name on the ground that your position as President is confidential commercial information, as you have not kept it confidential.

You may wish to consider requesting FDA to post your May 7, 2003 response to the Warning Letter under FDA's Warning letter pilot program. If you would like more information on the pilot program, you may consult the following URLs:

http://www.fda.gov/OHRMS/DOCKETS/98fr/03-15732.html;

http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01237.html.

Sincerely,

Joanne Binkley
Director, Division of Disclosure and Oversight Management
Office of Communication, Training and Manufacturers Assistance
CBER, FDA